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ORIGINAL PAPER

# Pilot Randomized Controlled Trial of Motivational Interviewing with Sexual Minority Male Couples to Reduce Drug Use and Sexual Risk: The Couples Health Project

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## Abstract

A randomized controlled trial evaluated the preliminary efficacy of a dyadically-delivered motivational interviewing (MI) intervention to reduce drug use and sexual risk in a sample of 50 sexual minority (cis)male (SMM) couples. In each couple, at least one partner was aged 18–29; reported drug use and sexual HIV transmission risk; and was HIV-negative. Couples were randomized to either the three-session MI intervention or an attention-matched control, with follow-up surveys completed at 3- and 6-months post-baseline. Between-group differences for all outcomes were non-significant in the overall sample. Subsequent moderation analyses indicated the intervention significantly reduced illicit drug use (excluding marijuana) at 3-month follow-up when either respondents ($B = -1.96$; interval rate ratio—*IRR* 0.02–1.22; $p = .001$), their partners ($B = -2.60$; *IRR* 0.01–0.64; $p = .004$), or both ($B = -2.38$; *IRR* 0.01–0.80; $p = .001$) reported high levels of baseline use. The intervention also reduced condomless anal sex (CAS) with casual partners when both partners reported high frequency baseline CAS ($B = -2.54$; *IRR* 0.01–0.83; $p = .047$). Findings provide initial evidence of the potential for MI to address drug use and sexual risk-taking among SMM couples at highest risk.
*Trial Registration* ClinicalTrials.gov (NIH U.S. National Library of Medicine) Identifier: #NCT03386110.

**Keywords** Marijuana · Club drug · HIV · Sexually transmitted infection · Gay and bisexual men

## Introduction

Rates of drug use and dependence are generally higher among sexual minority men (SMM) compared to their heterosexual counterparts [1, 2]. Across studies, the drugs most commonly reported include marijuana and a number of other illicit drugs, such as cocaine or crack, methamphetamine, ecstasy, ketamine, and/or gamma-hydroxybuterate (GHB) [1]. Therefore, the development of effective drug use interventions for SMM in relationships—including gay, bisexual and other men who have sex with men—is a public health priority.

In addition to the health risks inherent to drug use itself, drug use is a well-established correlate of sexual HIV transmission risk behavior. This is of substantial concern because SMM accounted for approximately 69% of all HIV diagnoses in the US in 2018 [3]. Earlier research indicated that 35–68% of new HIV infections among SMM were transmitted between main partners [4–6]. Estimated rates were as high as 79% among younger SMM (aged 18–29) [6]. More

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recent research has indicated that the likelihood of having condomless anal sex (CAS) with casual partners is comparable for single SMM and partnered SMM in non-monogamous sexual agreements [7, 8]. Moreover, some evidence suggests that SMM in monogamous relationships who break their agreement and engage in CAS with casual partners may actually do so more frequently than non-monogamous and single men [7].

There is consistent evidence that associations between drug use and sexual HIV transmission risk behavior generalize to SMM in relationships. Several studies have demonstrated that the use of a number of illicit drugs is associated with the occurrence or frequency of CAS with casual partners [e.g., 9–12]. This association held across relationship status and sexual agreements, and was significantly stronger among single and non-monogamous SMM [7]. In addition, a day-level association between illicit drug use and CAS with casual partners has recently been observed in dyadic data from SMM couples [13].

Findings related to marijuana and sexual risk-taking are mixed [e.g., 9, 14, 15]; but recent studies have demonstrated that marijuana is associated with a modest and statistically significant increase in the likelihood of CAS with casual partners above and beyond other illicit drug use [7, 12]. This finding has also been replicated in dyadic day-level data from SMM couples [13]. The findings of Starks et al. [7] provide some context for previous equivocal results. They found that marijuana predicted only the occurrence—not the frequency—of CAS and that the association was significantly weaker among men in non-monogamous relationships. They concluded that marijuana should be viewed as relevant to sexual behavior while acknowledging that its effect size was modest compared to other illicit drugs.

Motivational Interviewing (MI) [16] has demonstrated efficacy to address a wide range of health risk behaviors when delivered to individuals [17–19]. Additionally, there is substantial evidence that this approach is effective at reducing substance use when delivered in one-on-one counseling formats [20]. It has even been used successfully to achieve reductions in substance use and CAS with casual partners among SMM specifically [17, 21]. Unfortunately, follow-up analyses from the *Young Men's Health Project* indicated that SMM who were partnered at the time of intervention receipt may have benefited less from the individually-delivered MI intervention compared to SMM who are single [22].

Despite the general promise of MI-based interventions, their use with couples has been relatively rare. The studies performed to date generally viewed such work through the lens of a significant-other being involved as an adjunct participant in the substance use treatment of an identified client, with mixed results [23–26]. One of the challenges to implementing MI with couples is the absence of clear guidance for how providers should manage conflict in session and what providers should do when partners argue against change [27].

To address this challenge, Starks et al. [28, 29] drew on Interdependence Theory [30, 31] to derive processes and techniques unique to implementing MI with couples. This work adopted the novel premise that the couple was "the client" rather than identifying one partner in the couple as "the client" and the other as an "adjunct participant." This framework [28, 29] therefore provides a context for engaging couples where one or both partners in the relationship may use drugs to varying degrees.

Research informed by Interdependence Theory has shown that SMM in relationships use a variety of social control strategies to influence one another's health behavior, including behaviors involving sexual HIV transmission risk and substance use [32]. Partners are more successful at working together towards a shared health goal when they are more satisfied with, invested in and committed to their relationships. Interdependence Theory posits that this occurs because, when couples have better relationship functioning, partners are more likely to consider the consequences of their actions not just for themselves, but for their partner and their relationship overall. This motivates people to respond constructively in moments of conflict or disagreement [33, 34]. Among SMM specifically, relationship functioning is associated with the use of more positive (supportive) and fewer negative (aversive) social control techniques [32].

Building on these principles, Starks et al. [28] proposed that facilitating dyadic functioning is an essential process unique to MI with couples. MI traditionally conceives of four processes: engaging, focusing, evoking, and planning [16]. Starks et al. [28] suggested that facilitating dyadic functioning—a process characterized by eliciting the couple's strengths, activating pro-social exchanges between partners, and problem-solving around sources of conflict—was an additional essential component. Through subsequent qualitative analysis of session data, we derived techniques providers can use to mitigate conflict and support constructive accommodation in session [29]. This creates the opportunity for joint goal formation and planning.

While promising, this initial work on dyadic MI [28, 29] is, thus far, formative. The goal of the current study was to evaluate the preliminary efficacy of a brief MI intervention for SMM couples based on this initial work. The previous decade has seen substantial energy directed towards the development of couples-based HIV prevention interventions. Couples HIV testing and counseling (CHTC) [35, 36]—a service in which partners discuss HIV prevention, establish a sexual agreement, learn their HIV status, and develop a shared HIV prevention plan—is now a standard of care in the US. In addition, psychoeducational interventions with designated attention to drug use and sexual risk-taking for

SMM couples have demonstrated promise in reducing sexual transmission risk behavior [37–39].

The current study evaluates the potential of a novel MI intervention with couples, incorporating dyadic HIV testing into both conditions, to advance the field further. The primary hypothesis was that receipt of the MI condition would be associated with significant reductions in primary outcomes (frequency of illicit drug use and CAS with casual partners) and secondary outcomes (drug use related problems and frequency of marijuana use) relative to control. Secondarily, we examined the potential for baseline drug use frequency, drug use related problems, and CAS frequency to moderate treatment effects. These moderation analyses represent a post hoc preliminary examination of which couples are most likely to benefit from MI—a pernicious question in this area of research that is as yet unresolved. In addition, this is the first study to evaluate the potential efficacy of MI with couples using the methods and approach outlined by Starks et al. [28, 29]. This approach deviates from prior efforts by conceptualizing the couple—rather than an individual partner—as the identified client. The theoretical assumptions underlying the intervention would suggest that treatment efficacy may be a function of both partners' use.

## Methods

The *Couples Health Project* was a randomized controlled trial that enrolled participants between March, 2018 and March, 2020 in the New York City metropolitan area (NCT#03386110). Recruited participants completed a baseline assessment and follow-up assessments at 3- and 6-months post-baseline. Randomization to either the experimental MI intervention or an attention-matched education control condition occurred post-baseline.

### Participants

Preliminary eligibility was determined initially by individual- and couple-level characteristics reported by the index partner at screening. This included a relationship duration of 3 months or more. In addition, at least one partner in the couple was aged 18 to 29; at least one was HIV-negative; at least one used marijuana or illicit drugs (cocaine, crack, methamphetamine, ketamine, GHB, psychedelics or hallucinogens) or misused prescription drugs in the past 30 days; and at least one had CAS with a casual partner, a non-monogamous main partner, or a serodiscordant main partner in the past 30 days.

Age and the exclusion criteria of the occurrence of intimate partner violence were verified by individual report of both partners at baseline. Age for both partners was verified by inspection of personal identification during consent procedures. Couples were excluded if either partner reported serious physical or sexual intimate partner violence and did not feel safe in their relationship on the baseline survey.

### Procedures

The study utilized an index participant approach to recruit couples [40]. Participants accessed the screener after seeing online advertisements for the study or recruitment in-person. Online recruitment efforts included advertisements on websites (e.g., Facebook) and popular geosocial networking apps for gay, bisexual, trans, and queer people seeking out sexual partners. Participants clicking on an ad progressed to a screening survey that assessed preliminary eligibility criteria and gathered contact information. In addition, study staff went in-person to bars, nightclubs, and other social events for SMM in the metropolitan area and screened participants on an iPad device using the same screener used in online recruitment.

Through June 2019, preliminarily eligible index participants were contacted by phone to complete a study specific screener. To accommodate participant communication preferences, this was converted to an online survey in July, 2019. Study staff provided a link to the study specific screener by email or text message. Eligible index participants then scheduled a baseline assessment at a time their partner could also attend. Prior to the baseline appointment, the index participant received an email containing a link to an at-home survey as well as a comparable email to be forwarded to their partner. The link directed participants to written consent information. Those consenting advanced into the study.

At the start of the baseline appointment, a research assistant (RA) completed a verbal review of consent procedures with each partner individually; obtained written documentation of consent; and verified age. Partners completed assessments in separate assessment rooms. The baseline assessment included a second Qualtrics survey containing measures not administered in the survey completed at-home. In addition, participants completed an RA-administered timeline follow-back (TLFB) interview of sexual behavior and substance use in the past 30 days following procedures outlined by Sobell and Sobell [41] and similar to others [e.g., 21, 42]. Participants first identified "anchor dates" or significant events that the RA recorded on a calendar depicting the past 30 days. If the participant was taking pre-exposure prophylaxis (PrEP), the RA then recorded all days the participant indicated a missed dose. Next, the RA recorded days the participant used marijuana or other illicit drugs. Finally, the RA recorded days the participant indicated sexual activity. These entries included partner type (main or casual), the sex act performed (e.g., anal insertive, anal receptive), and whether a condom was used. The baseline assessment concluded with collection of biological specimens (fingernail

samples for drug use as well as urine samples and rectal swabs for gonorrhea and chlamydia).

Regardless of condition, participants had the option to complete Session 1 immediately after their baseline visit (time-permitting) or to reschedule in the following week. Sessions 2 and 3 in both conditions were subsequently completed in the 4 weeks following baseline. Dyadic participation was required for session completion.

After the 3-session intervention versus control condition described below, follow-up assessments 3- and 6-months post-baseline were also scheduled separately with each partner. Both 3- and 6-month follow-up visits involved a Qualtrics-administered survey, TLFB interview and collection of drug use fingernail specimens. Collection of rectal and urethral specimens for STI testing for gonorrhea and chlamydia was conducted at the baseline and 6-month follow-up visit. Collection of follow-up fingernail specimens and STI testing was partially disrupted by the COVID-19 epidemic. Specifically, due to social distancing restrictions, in-person data collection was suspended on March 15, 2020. Although all baseline assessments were completed by this time, follow-up assessments (which included survey and TLFB completion) after this date could only be conducted remotely over Zoom and could not involve specimen collection.

Compensation was delivered as cash or Amazon gift card based upon participant preference and social distancing constraints. Each participant received $20 for completion of TLFB and survey assessments and $10 for fingernail or toenail samples at baseline, 3- and 6-month follow-up. In addition, participants received $20 for providing biological samples for urethral and rectal STI testing at baseline and 6-month follow-up. Participants were compensated $20 for each MI or Education session completed. All procedures were approved by the Institutional Review Board of Hunter College of the City University of New York.

## Ethical Considerations

A number of salient ethical considerations informed the procedures described above. Two procedures were intended to assess the possibility that one partner might feel pressured or coerced into participating by the other. First, the at-home baseline survey asked participants whether, "your partner or anyone else pressured or coerced you into completing this survey?" To be eligible, participants had to indicate "no" to this question. Second, RAs completed the in-person review of informed consent (and obtained written documentation of consent) with each partner individually. Beyond the consent process, study procedures were designed to preserve confidentiality of individual partners' assessment data. All assessments were conducted individually. At baseline, partners came to the appointment together, but completed surveys and interviews in private rooms independently of one another. All RAs were trained to avoid implicitly or explicitly disclosing one partner's responses to the other. Interventionists and educators were not permitted to access data provided by individual participants in assessment to minimize the potential that assessment data would influence intervention sessions or that breaches of confidentiality would occur.

## Study Site

All appointments and condition sessions were conducted at an academic research center located in New York City. The center furnished private assessment rooms and intervention rooms to conduct sessions with couples together. The center was equipped with a phlebotomy room and facilities necessary for the collection, storage, and shipping of biological specimens.

## Randomization

After baseline, participants were randomized to receive either the MI intervention or the education control condition. Both conditions involved dyadic participation. Therefore, couples—rather than individuals—were randomized. Randomization was implemented through a Qualtrics survey programmed for equal allocation and stratified on age discrepancy (3 years or more versus less than 3 years); racial and ethnic composition (both partners identified as majority White versus either partner identifying as a racial or ethnic minority); and relationship duration (2 years or more versus less than 2 years).

## Masking

Assessors were blind to condition assignment. Due to the nature of the intervention and education experience, it was not possible to blind the intervention or education staff delivering the condition sessions. Participants were not informed about the condition to which they were assigned, and recruitment and baseline procedures prior to randomization did not vary by condition.

## Condition Description

*Motivational Interviewing* comprised 3 sessions, each lasting 60–75 min. Session content and structure followed a protocol developed in our formative research [28, 29]. The interventionists had prior training at the masters or doctoral level in social work or clinical psychology. The first author trained and supervised all interventionists in the delivery of MI to couples incorporating processes and techniques identified in our previous research [28, 29].

Providers with active cases met weekly with the first author for supervision. MI fidelity was also assessed using the Motivational Interviewing Treatment Integrity system [43] with supplementary codes developed by Starks et al. [44] to assess fidelity to couples MI specifically. A group of 4 coders who were not involved in intervention delivery evaluated a total of 25 sessions (45% of MI sessions conducted). The average ratings for technical ($M = 3.52$, $SD = 0.53$) and relational ($M = 4.16$, $SD = 0.53$) global scores were above the threshold for "fair" performance. This threshold was met in > 90% of sessions for both global rating domains. The average reflection to question ratio was 1.48 ($SD = 0.55$), also exceeding the threshold for "fair" performance. On average, 36% of reflections were complex reflections directed to individual partners ($SD = 0.16$). While this is below the threshold for "fair performance" typically applied to the percentage of complex reflections in individual MI delivery, the use of complex reflections must be understood in the context of dyadic reflections. These are reflections that encompass content from both partners or which are directed specifically to the couple. These reflections accounted for 43% of reflections on average ($SD = 0.19$). As a result, only 20% of reflections on average were simple reflections directed to individual partners.

- Session 1 opened with an emphasis on engagement and facilitating dyadic functioning. The interventionist established rapport and discussed strengths and weaknesses in dyadic functioning. They then introduced the target behavior of substance use and the couple completed a calendar describing their use in the past month. This served as a starting point to evoke change talk. The session ended with the development of goals for the coming week.
- Session 2 began with a review of goals as well as successes and challenges in the couple's interactions in the previous week. The couple then completed a card-sort exercise that highlighted shared values and joint-goals. Then, the session focused either on sex within the primary relationship or sex with outside partners based upon the couple's needs and goals. The discussion examined intersections of drug use and sexual behavior as interventionists sought to evoke change talk related to substance use and HIV prevention. The session ended with goal development for the upcoming week.
- Session 3 began with a review of goals as well as successes and challenges in the couple's interactions in the previous week. It then focused on substance use, sex within the primary relationship, or sex with outside partners based upon the couple's goals. HIV-negative partners were offered the opportunity to complete HIV testing as a couple. The session ended with a discussion of long-term goals and related planning. HIV testing was performed using the Alere Determine Ab/Ag Testing Kit®. Test results via this rapid assay were available in 20 min and delivered to participants immediately during the session.

*Dyadic health education (control)* was comprised of three sessions, each lasting 45–75 min and delivered to the couples in-person. Educators were undergraduate and masters-level project staff with extensive training in sexual health education and HIV testing. Content was delivered in-person to the couple, structured through the use of PowerPoint presentations, and supplemented with relevant publically-sourced video content. Intervention fidelity was monitored through a review of session recordings by a masters-level supervisor who completed a checklist assessing the presence of session content and adherence to delivery protocols. The supervisor subsequently provided weekly in-person feedback and coaching to educators with active cases.

- Session 1 provided an overview of psychological research on sex, relationships, and sexual health among men who have sex with men. Content included information on sexual risk reduction strategies.
- Session 2 provided information related to substance use generally and within SMM communities specifically. Content included details on the impact of substance use on sexual behavior and performance.
- Session 3 consisted of Couples' HIV Testing and Counseling following the CDC's protocol [45]. Similar to the MI condition, HIV testing was performed using the Alere Determine Ab/Ag Testing Kit®.

## Measures

### Demographics

Participants reported their age, HIV status, PrEP uptake, sexual identity (gay, bisexual, or other), race/ethnicity (Black, Latino, White, Other/Mixed; we collapsed several groups, e.g., Native American, Asian, into an Other/Mixed category given the small number of participants), income (below $40,000 and $40,000 or above annually), education (less than college or college and above), and relationship length.

Similar to other studies [e.g., 8, 46], sexual arrangement was assessed using a single item: "Regardless of your sexual agreement, how do you and your partner handle sex outside your relationship?" Responses were used to create a couple-level variable derived from both partners' responses. Couples were categorized as monogamous when both partners agreed that their arrangement did not permit sex with outside partners; monogamish when both partners agreed that sex with outside partners only occurred when both partners

were present; open when at least one partner indicated that their arrangement involved sex outside the relationship; and discrepant when partners had divergent impressions of their sexual arrangement.

#### PrEP Adherence

Participants categorized as on PrEP and adherent indicated having a current PrEP prescription and reported missing fewer than 13 PrEP doses in the prior 30 days on the TLFB interview.

### Primary outcomes

#### Other Illicit Drug Use Frequency

During their TLFB interview, participants reported days they used illicit drugs (e.g., cocaine/crack, ecstasy/MDMA, GHB, ketamine, and crystal methamphtamine) in the past 30 days. These variables were aggregated into a count variable quantifying the number of days participants reported the use of these illicit drugs. The convergent validity of TLFB self-reported drug use frequency was evaluated by correlation with objective metrics of drug use obtained from fingernail assays. Drug testing was completed using the Nail Testing Panel from the United States Drug Testing Lab® (USDTL).

#### Condomless Anal Sex with Casual Partners

TLFB responses were aggregated to create a day-level variable that indicated the number of times the participant had CAS with a casual partner (insertive or receptive) during the assessment period (past 30 days). Casual sex partners were defined as any partner excluding the identified main partner who was enrolled into the study with the participant. The convergent validity of TLFB self-reported sexual behavior was evaluated by correlation with rectal and urethral gonorrhea and chlamydia test results. These bacterial STIs served as an objective proxy-indicator of sexual behaviors that might also transmit HIV infection. Urine samples and rectal self-swabs were tested with Hologic Aptima® test kits.

### Secondary Outcomes

#### Marijuana Use Frequency

During their TLFB, participants indicated the days they used any form of marijuana in the past 30 days. Responses were aggregated into a single variable indicating the total number of days marijuana was used.

*Problematic drug use* was assessed using the 10-item Drug Abuse Screening Test (DAST-10) [47]. Participants who indicated the use of drugs were subsequently asked to indicate the presence or absence of nine symptoms associated with drug use. Responses were summed to produce a count of problems. Those participants who did not indicate the use of any substances assessed were assigned a value of zero.

### Analytic Plan

A series of bivariate analyses conducted using the generalized estimating equations function within SPSS (version 25) evaluated the success of randomization and the presence of differential attrition. These models controlled for the nesting of partners within couple and permitted the specification of normal, logistic, and count distributed outcomes. Models evaluating the success of randomization included condition (MI-intervention versus control) as the sole predictor of baseline characteristics. Analogous models evaluating differential attrition included a dichotomous predictor indicating whether or not a participant was retained in a particular follow-up as a predictor of baseline characteristics.

Multi-level models calculated in Mplus [version 8.2; 48] evaluated primary hypotheses about treatment effects. These models controlled for the nesting of participants within couples and permitted the specification of logistic and count (Poisson or negative-binomial) distributions as appropriate. Full-information maximum likelihood estimation was utilized to retain all cases in a true intent-to-treat paradigm. For each outcome, 3- and 6-month values were predicted by treatment condition.

The hypothesis that baseline frequency of drug use or CAS with casual partners may moderate the effects of treatment was evaluated using the Actor-Partner Interdependence Model (APIM) framework [49]. Models incorporated participants' own baseline report of the outcome (actor scores) as well as their partners' report (partner scores) at Level 1. Interactions among actor and partner baseline scores and treatment condition were also included at Level 1. This included the 3-way interaction term as well as all possible 2-way interactions. A natural log (i.e. $\ln(X+1)$) transformation was used to address skew in these predictor variables.

For models involving count-distributed outcomes, effect size was calculated using procedures outlined by Larsen and Merlo [50] for the calculation of an Interval Odds Ratio. When multi-level models utilize log-link functions and allow a random variance at Level 2, direct exponentiation of the Level 2 regression coefficient does not produce an accurate estimate of the between-group difference. The Interval Odds Ratio provides an alternative metric. It represents the 80%

confidence interval for the odds ratio comparing any one randomly selected participant in the treatment condition to one in the control condition accounting for cluster-level variability. In this instance, application of the IOR formula results in an Interval Rate Ratio (IRR) given the count nature of the outcome. When the interval is narrow, it implies that the rate ratio comparing any participant in the treatment condition to one in the control condition is relatively consistent. In contrast, wider intervals imply that the effect of treatment varies more across couples and therefore accounts for less variance in the outcome.

## Results

Figure 1 contains the CONSORT flow detailing enrollment and retention across the study. In total, 5931 potential index cases were screened. Of these, 3330 (60.4%) were ineligible because they were outside the geographic catchment area of the study. Another 865 (15.7%) were ineligible because they failed to meet at least one of the specified criteria for enrollment. Of the remaining participants, 159 (2.9%) were unable to recruit their partner and 1157 (20.8%) otherwise eligible participants declined to participate. Baseline assessment procedures were initiated

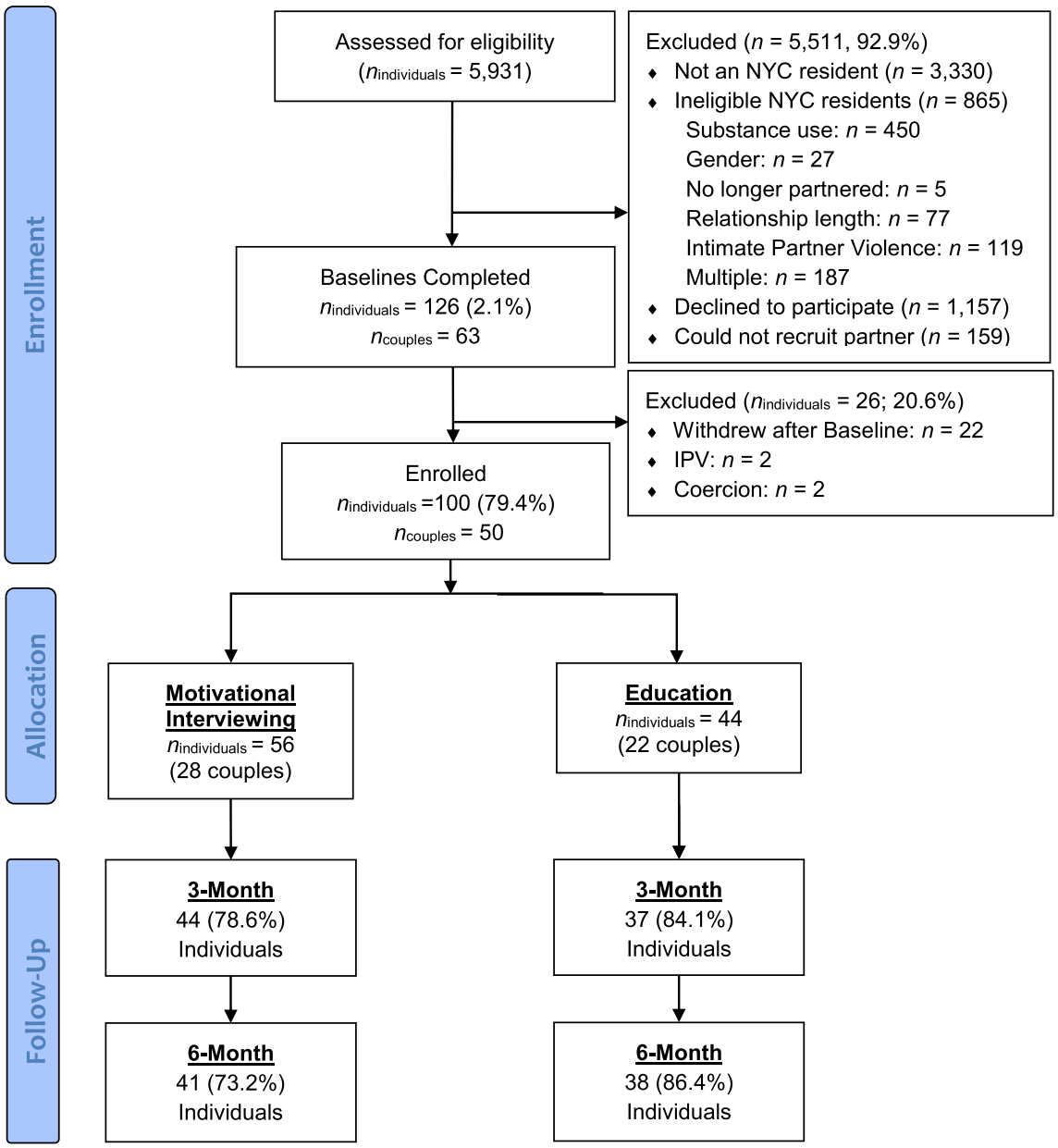


**Fig. 1** Consolidated standards of reporting trials (CONSORT) study flow

**Table 1** Baseline sample characteristics

| | Total ($n=100$) | Motivational interviewing ($n=56$) | Education ($n=44$) | Between-group difference | | Partner similarity | |
|---|---|---|---|---|---|---|---|
| | *n (%)* | *n (%)* | *n (%)* | *Wald* $\chi^2$ | *p* | κ | *p* |
| Race and ethnicity | | | | $\chi^2(3)=2.180$ | .536 | .229 | .013 |
| White/European | 58 (58) | 33 (58.9) | 25 (56.8) | | | | |
| Black/African American | 11 (11) | 5 (8.9) | 6 (13.6) | | | | |
| Latino | 22 (22) | 11 (19.6) | 11 (25.0) | | | | |
| Other | 9 (9) | 7 (12.5) | 2 (4.5) | | | | |
| Education | | | | 2.647 | .104 | .064 | .639 |
| Less than 4 year degree | 70 (70) | 43 (76.8) | 27 (61.4) | | | | |
| 4 year degree or more | 30 (30) | 13 (23.2) | 17 (38.6) | | | | |
| Annual income | | | | 0.722 | .395 | .224 | .115 |
| < $40,000 | 50 (50.5) | 26 (46.4) | 24 (55.8) | | | | |
| $40,000 or more | 49 (49.5) | 30 (53.6) | 19 (44.2) | | | | |
| HIV status | | | | 0.179 | .672 | − .111 | .267 |
| Negative or unknown | 90 (90) | 51 (91.1) | 39 (88.6) | | | | |
| Positive | 10 (10) | 5 (8.9) | 5 (11.6) | | | | |
| PrEP adherence (among HIV-negative men) | | | | 0.045 | .832 | .475 | .001 |
| 57% adherent or more | 43 (47.8) | 24 (47.1) | 19 (48.7) | | | | |
| < 57% adherent or no PrEP | 47 (52.2) | 27 (52.9) | 20 (51.3) | | | | |
| Sexual arrangement | | | | $\chi^2(3)=0.979$ | .806 | NA | |
| Monogamous | 8 (8) | 4 (7.1) | 4 (9.1) | | | | |
| Monogamish | 24 (24) | 12 (21.4) | 12 (27.3) | | | | |
| Open | 58 (58) | 34 (60.7) | 24 (54.5) | | | | |
| Discrepant | 10 (10) | 6 (10.7) | 4 (9.1) | | | | |
| | *M (SD)* | *M (SD)* | *M (SD)* | *Wald* $\chi^2$ | *p* | ICC | *p* |
| Age (years) | 28.62 (6.11) | 28.91 (6.12) | 28.25 (6.15) | 0.392 | .531 | − .262 | .966 |
| Relationship duration (months) | 33.7 (29.30) | 33.59 (31.72) | 33.89 (27.40) | 0.001 | .971 | NA | |

Unless otherwise indicated, all *Wald* $\chi^2$ have 1 degree of freedom

*PrEP* pre-exposure prophylaxis, *DAST-10* drug abuse screening test-10, *CAS* condomless anal sex, *NA* Similarity measure not applicable because both partners have the same value on the variable

with 63 couples and 50 of these were eligible and randomized to condition following baseline. Table 1 displays characteristics for randomized couples.

## Equivalence Checks

*Randomization checks* indicated that the two conditions were equivalent with respect to demographic characteristics. Between-condition differences in drug use and sexual behavior variables assessed at baseline were also largely non-significant. There was one exception to this. The frequency of other illicit drug use in the past 30 days reported by participants in the MI condition ($M=3.36$; $SD=8.46$) was significantly higher than that reported by participants in the education control condition ($M=0.84$; $SD=2.38$; *Wald* $\chi^2(1)=3.98$, $p=0.046$). Notably, the odds of other illicit drug use were equivalent across conditions (*Wald* $\chi^2(1)=0.01$, $p=0.91$), indicating that the significant between-group differences in frequency were not an artifact of differences in prevalence. As a result, models predicting other drug use adjusted for actor and partner baseline other illicit drug use frequency.

*Analyses of differential attrition* indicated that retention at 3- and 6-month follow-up was not significantly associated with intervention condition. There were no demographic differences between participants retained at 3-month follow-up and those who did not complete this visit. With respect to outcome variables, participants who completed the 3-month follow-up reported significantly more frequent use of other illicit drugs at baseline ($M=2.59$; $SD=7.21$) than those who did not complete the follow-up ($M=0.72$; $SD=2.19$; *Wald* $\chi^2(1)=6.20$, $p=0.01$). A follow-up test which included a

treatment by other illicit drug use interaction term indicated that this effect did not differ significantly between conditions ($B_{interaction} = 1.29$; 95%CI − 1.28, 3.85; $p = 0.326$) mitigating concerns about threats to internal validity. No other outcome variables were associated with retention at 3-month follow-up. No baseline demographic characteristics or outcome variables predicted retention at 6-month follow-up.

Overall, 21% of 3-month follow-ups (17 out of 82) and 46% of 6-month follow-ups (36 of 79) were completed during the COVID-19 pandemic, after March 15th 2020. While follow-up retention was equivalent across conditions, those in the couples MI condition were significantly more likely to complete their 3- and 6-month follow-ups remotely while the COVID-19 pandemic was ongoing. By chance in the stratified randomization scheme, 5 of these last 6 couples recruited were assigned to the MI condition. When these 6 couples are excluded from analyses, the probability of completing 3- and 6-month follow-ups while the pandemic was ongoing did not differ significantly across groups.

### Session Retention

There were no significant between-group differences in completion of Session 1 or 2. Of the 28 couples assigned to the MI condition, 24 (85.7%) completed Session 1. Meanwhile, 20 (90.9%) couples randomized to the education control condition completed Session 1 (Fisher's exact test = 0.683). In the Motivational Interviewing condition, 17 couples (60.7%) completed Session 2 compared to 19 couples (86.4%) in the control condition (Fisher's exact test = 0.061). There were significant between-group differences in Session 3 completion. Among couples in the MI condition, 14 (50%) completed Session 3 while 19 (86.4%) completed Session 3 in the control condition (Fisher's exact test = 0.008). The drop-off in session completion between Session 2 and 3 was not significantly different between conditions. Of the 17 couples in the MI condition who did Session 2, 14 (82.4%) completed Session 3. This does not differ significantly from the education control condition where 100% of couples who completed Session 2 also completed Session 3 (Fishers exact test = 0.095).

Session retention for the last 6 couples enrolled was conceivably impacted by COVID-19. These couples had not completed all of their sessions at the time of locally imposed shut-downs and their intervention windows were still open. Of these last 6 couples, one received 2 sessions; 4 received 1 session; and 1 couple was unable to complete any sessions. As mentioned previously, 5 of these couples were assigned to the MI condition, had 4 of these couples completed Session 3, the probability of session completion would not have differed significantly across conditions.

## Correspondence of Self-report and Biological Indicators

Results of analyses examining the correspondence of self-report and biological markers of drug use did not indicate under-reporting concerns. At baseline, samples were available from 72 participants. Of these, one (1.4%) tested positive for marijuana use but did not report it; 6 (8.3%) tested positive for either methamphetamines or cocaine but reported no use of other illicit drugs. At 3-month follow-up, 49 participants provided samples. Of these, one (2.0%) tested positive for marijuana but did not report it; meanwhile, 4 (8.2%) tested positive for methamphetamine or cocaine but reported no use of other illicit drugs. At 6-month follow up, 33 participants provided biological samples. Of these, 2 (6.1%) tested positive for marijuana but did not report it; meanwhile, 2 (6.1%) tested positive for cocaine or methamphetamine but reported no use of other illicit drugs.

Similarly, tests of estimated marginal means conducted using the Generalized Estimating Equation function in SPSS (and specifying a negative binomial distribution for CAS with casual partners) indicated that at baseline, participants who tested positive for any bacterial STI reported significantly more instances of CAS with casual partners ($M = 4.09$, $SE = 0.79$) compared to those who did not ($M = 1.52$, $SE = 0.31$; $Wald\ \chi^2(1) = 10.86$, $p = 0.001$). Due to COVID-19 related disruptions in biological specimen collection, STI data were available for 37 participants at follow-up, substantially diminishing power to detect associations with CAS with casual partners. While the between-group difference was non-significant, the mean reported frequency of CAS with casual partners was larger among men who tested positive for any STI ($M = 2.31$, $SE = 0.81$) compared to those who tested negative for all STIs ($M = 1.35$, SE = 0.37; $Wald\ \chi^2\ (1) = 1.50$, $p = 0.221$).

## Direct Treatment Effects

Table 2 contains results of analyses examining cross-sectional between-group differences on primary and secondary outcomes assessed at Baseline, 3- and 6-month follow-up. Based upon results of randomization and attrition checks, the models predicting use of other illicit drugs included actor and partner effects of baseline use frequency. There were no statistically significant between-group differences at either follow-up time-point for any outcomes in these models.

## Moderation Analyses

Tests of moderation were conducted for primary and secondary outcomes. Table 3 contains the results of moderation

**Table 2** Between-group differences in primary and secondary outcomes

| | Motivational Interviewing | Education | *B* | *95% CI* | *p* |
|---|---|---|---|---|---|
| | *M(SD)* | *M(SD)* | | | |
| Primary outcomes | | | | | |
| *Other illicit drugs* | | | | | |
| Baseline | 3.36 (8.46) | 0.84 (2.38) | 1.38 | (0.02, 2.75) | .046 |
| 3 Month[a] | 3.13 (8.41) | 0.73 (1.37) | 1.19 | (− 0.15, 2.54) | .081 |
| 6 Month[a] | 1.17 (3.79) | 0.58 (1.24) | 0.70 | (− 0.49, 1.89) | .251 |
| *CAS with casual partners* | | | | | |
| Baseline | 1.68 (2.78) | 1.68 (2.34) | − 0.002 | (− 0.67, 0.67) | .995 |
| 3 Month | 2.13 (3.61) | 1.49 (3.70) | 0.36 | (− 0.65, 1.37) | .364 |
| 6 Month | 0.88 (1.66) | 1.05 (1.82) | − 0.18 | (− 1.15, 0.78) | .628 |
| Secondary outcomes | | | | | |
| *Marijuana* | | | | | |
| Baseline | 9.61 (11.93) | 7.02 (10.24) | 0.31 | (− 0.30, 0.93) | .316 |
| 3 Month | 9.62 (11.83) | 5.95 (10.24) | 0.48 | (− 0.18, 1.44) | .154 |
| 6 Month | 10.00 (12.43) | 7.89 (11.75) | 0.24 | (− 0.44, 0.92) | .496 |
| *DAST-10* | | | | | |
| Baseline | 2.02 (2.05) | 1.61 (1.22) | 0.22 | (− 0.18, 0.66) | .279 |
| 3 Month | 2.48 (2.10) | 1.86 (1.42) | 0.28 | (− 0.07, 0.64) | .115 |
| 6 Month | 1.90 (1.91) | 1.62 (1.26) | 0.16 | (− 0.29, 0.61) | .482 |

*CI* confidence interval, *M* mean, *SD* standard deviation; Other Illicit Drugs include cocaine/crack, ecstasy, GHB, ketamine, and methamphetamine; *DAST-10* drug abuse screening test-10, *CAS* condomless anal sex

[a]Tests of between group differences controlled for baseline other illicit drug use frequency

analyses for these outcomes where significant interactions between treatment and actor or partner baseline use were observed. This included other illicit drug use frequency, frequency of CAS with a casual partner, and DAST-10 scores.

### Moderation Results for Primary Outcomes

**Other Illicit Drug Use** The 3-way interaction among actor and partner baseline use and treatment condition was statistically significant in the prediction of other illicit drug use frequency at 3-month ($B = 1.79$; 95%CI 0.49. 3.09, $p = 0.007$). This interaction is depicted in Fig. 2. The overall pattern arising from the interaction was that the intervention effect increased with baseline use. When both partners in a relationship reported no use of other illicit drugs (both actor and partner use = 0), the intervention effect was non-significant ($B = 0.55$; 95%CI − 1.87, 2.97; $p = 0.656$). In contrast, the intervention effect was statistically significant when either actor ($B = -1.96$; 95%CI − 3.16, − 0.76; $p = 0.001$) or partner ($B = -2.60$; 95%CI − 4.37, − 0.83; $p = 0.004$) other illicit drug use frequency at baseline was 1 standard deviation above the mean. This equates to a ln(drug use frequency + 1) of 1.25. Reversing the log transformation and linear shift directly, this would equate to approximately 2.5 days of use in the past 30 days. The intervention effect was also statistically significant when both partners in the relationship reported high frequency of other illicit drug use ($B = -2.38$; 95%CI − 3.75, − 1.01; $p = 0.001$). In other words, MI was associated with significant reductions in other illicit drug use among men in couples where at least one partner reported a high level of use at baseline. At 6-month follow-up, the effect of treatment was non-significant and there was no evidence of significant interactions with baseline use.

When both actor and partner baseline illicit drug use were low, the IRR for the intervention effect was 0.20 to 14.96. Consistent with the non-significant effect of intervention at this level of actor and partner use, the IRR is wide indicating substantial variability in the effect across couples. It also includes 1.0, suggesting it does not account for a substantial amount of couple-level variability. In contrast, the intervention effect at high levels of actor baseline illicit drug use was associated with an IRR of 0.02, 1.22. While this IRR includes 1.0, suggesting that the amount of cluster-level variability in drug use accounted for is modest, it has narrowed considerably. The IRR for the treatment effect at high levels of partner baseline illicit drug use was: 0.01 to 0.64 and at high levels of both actor and partner baseline illicit use the IRR was 0.01 to 0.80. Here the IRRs have narrowed further and exclude 1.0, suggesting that the effect of MI was more consistent and accounted for a substantial proportion of couple-level variability in the outcome.

**CAS with Casual Partners** There were no indications of significant interactions involving the treatment effect on 3-month frequency of CAS with casual partners. With regard to frequency at 6-month follow-up, the 3-way interaction among actor and partner baseline frequency of CAS with casual partners and treatment condition was statistically significant ($B = -1.70$; 95%CI − 3.14, − 0.27; $p = 0.020$). This interaction is depicted in Fig. 3. The overall pattern was that the intervention effect was maximized among couples where both partners reported relatively high rates of CAS with casual partners at baseline. When both partners in a relationship reported no CAS with casual partners at baseline (both actor and partner frequency = 0), the intervention

**Table 3** Post hoc tests of interactions between treatment condition and baseline outcome values

| | Other illicit drugs | | | CAS with casual partners | | | DAST-10 | | |
|---|---|---|---|---|---|---|---|---|---|
| | *B* | *95% CI* | *p* | *B* | *95% CI* | *p* | *B* | *95% CI* | *p* |
| | 3 month follow-up | | | 3 month follow-up | | | 3 month follow-up | | |
| Level 1 | | | | | | | | | |
| *Baseline outcome value* | | | | | | | | | |
| Actor | 3.45 | (1.63, 5.28) | < .001 | 0.63 | (− 0.27, 1.54) | .168 | 0.48 | (0.37, 0.59) | < .001 |
| Partner | 1.70 | (− 0.20, 3.59) | .079 | − 0.45 | (− 1.97, 1.06) | .557 | 0.03 | (− 0.25, 0.32) | .824 |
| *Interactions* | | | | | | | | | |
| Condition × actor value | − 2.02 | (− 3.95, − 0.08) | .041 | 0.57 | (− 0.65, 1.43) | .419 | − 0.14 | (− 0.29, 0.00) | .050 |
| Condition × partner value | − 2.57 | (− 4.73, − 0.41) | .020 | 0.72 | (− 0.74, 1.47) | .473 | 0.13 | (− 0.17, 0.44) | .386 |
| Actor × partner value | − 1.45 | (− 2.68, − 0.3) | .020 | 0.68 | (− 0.42, 1.77) | .225 | − 0.02 | (− 0.11, 0.06) | .589 |
| Condition × actor × partner | 1.79 | (0.49, 3.09) | .007 | − 0.54 | (− 1.85, 0.77) | .417 | − 0.01 | (− 0.09, 0.08) | .846 |
| Level 2 | | | | | | | | | |
| Condition (ref = control) | 0.55 | (− 1.87, 2.97) | .656 | 0.21 | (− 2.09, 1.66) | .825 | 0.13 | (− 0.40, 0.66) | .630 |
| | Other illicit drugs | | | CAS with casual partners | | | DAST-10 | | |
| | *B* | *95% CI* | *p* | *B* | *95% CI* | *p* | *B* | *95% CI* | *p* |
| | 6 month follow-up | | | 6 month follow-up | | | 6 month follow-up | | |
| Level 1 | | | | | | | | | |
| *Baseline outcome value* | | | | | | | | | |
| Actor | 1.99 | (− 0.39, 4.38) | .101 | 0.39 | (− 0.65, 1.43) | .461 | 0.43 | (0.19, 067) | < .001 |
| Partner | − 0.73 | (− 3.19, 1.74) | .563 | 0.37 | (− 0.74,v1.47) | .516 | 0.27 | (0.01, 0.52) | .040 |
| *Interactions* | | | | | | | | | |
| Condition × actor value | − 0.94 | (− 3.62, 1.74) | .491 | 1.13 | (− 0.26, 2.51) | .112 | − 0.10 | (− 0.37, 0.17) | .451 |
| Condition × partner value | 1.69 | (− 1.03, 4.40) | .223 | 0.78 | (− 0.72, 2.28) | .308 | − 0.04 | (− 0.34, 0.27) | .820 |
| Actor × partner value | 0.21 | (− 1.57, 1.99) | .819 | 0.25 | (− 0.80, 1.30) | .643 | − 0.08 | (− 0.16, 0.01) | .096 |
| Condition × actor × partner | − 0.36 | (− 2.26, 1.53) | .707 | − 1.70 | (− 3.14, − 0.27) | .020 | 0.05 | (− 0.05, 0.14) | .324 |
| Level 2 | | | | | | | | | |
| Condition (ref = control) | 0.09 | (− 2.41, 2.59) | .945 | − 0.54 | (− 2.35, 1.27) | .561 | − 0.02 | (− 0.77, 0.74) | .969 |

*CI* confidence interval, *DAST-10* drug abuse screening test-10, *CAS* condomless anal sex

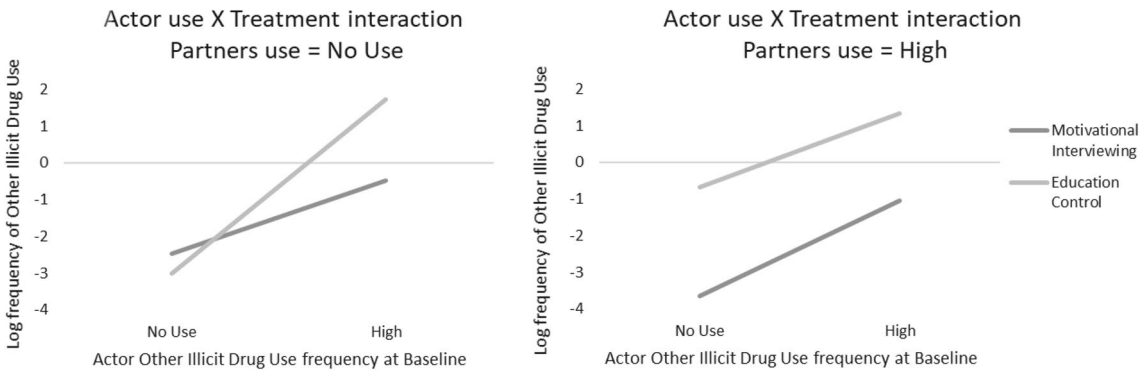


**Fig. 2** Other Illicit Drug Use frequency at 3-month follow-up: interactions among condition, actor baseline report, and partner baseline report

effect was non-significant ($B = -0.54$; 95%CI − 2.35, 1.27; $p = 0.561$). Simple main effects were evaluated at "low" (no instances) and "high" (1.5 standard deviations above the mean) levels of frequency of CAS with Casual Partners at

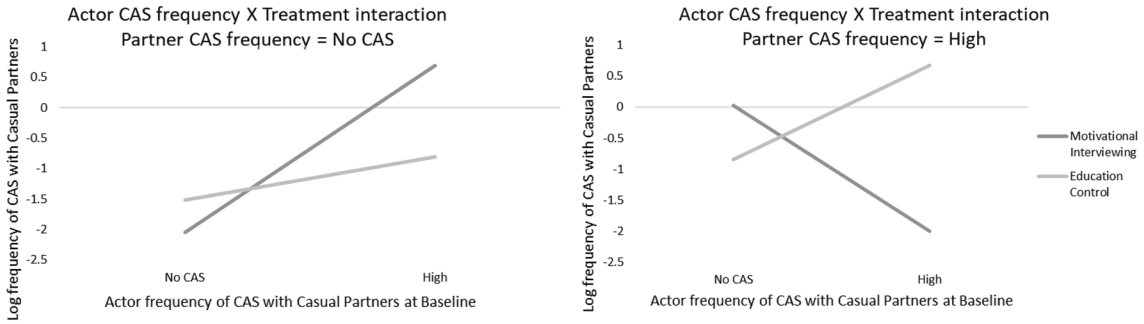


**Fig. 3** CAS with casual partners frequency at 6-month follow-up: interactions among condition, actor baseline report, and partner baseline report

baseline. In this instance, 1.5 standard deviations above the mean equates to a ln(CAS frequency + 1) of 1.81. Reversing the log transformation and linear shift directly, this would equate to about 5.13 instances of CAS with casual partners in the past 30 days reported at baseline.

The intervention effect was non-significant when only actor CAS with casual partner frequency was high ($B = 1.45$; 95%CI − 0.27, 2.88; $p = 0.098$) as well as when only partner CAS with casual partner frequency was high ($B = 0.87$; 95%CI − 1.08, 2.82; $p = 0.381$). In contrast, the intervention effect was statistically significant when both actor and partner CAS with casual partner frequency was 1.5 standard deviations above the mean or greater ($B = -2.54$; 95%CI − 5.05, − 0.04; $p = 0.047$).

The intervention effects were non-significant when both actor and partner CAS with casual partner frequency was low and in circumstances where only actor or partner frequency was high. Consistent with this, IRR's for the treatment effect under these 3 circumstances were comparatively wide and inclusive of the value 1.0 ($IRR_{\text{low actor and partner CAS frequency}} = 0.06$ to 6.19; $IRR_{\text{high actor CAS frequency}} = 0.41$ to 44.66; and $IRR_{\text{high partner CAS frequency}} = 0.23$ to 25.19). In contrast, when both actor and partner CAS with casual partner frequency was high at baseline the IRR for the treatment effect on CAS was 0.01 to 0.83. This indicated that among couples where both partners reported high frequency CAS with casual partners at baseline, the treatment effect was consistent and accounted for a substantial amount of variance between couples.

### Moderation Analyses of Secondary Outcomes

**Marijuana Use** There was no evidence of statistically significant interactions between actor and partner use at baseline and marijuana use frequency at either follow-up. At both 3- and 6-months, the 3-way interaction term and all 2-way interactions were non-significant.

**DAST-10** At 3-month follow-up, the 3-way interaction was non-significant as was the 2-way interaction between partner DAST-10 scores and the intervention effect as well as the 2-way interaction between the actor and partner DAST-10 scores. In contrast, the interaction between actor DAST-10 scores and treatment was at the threshold for statistical significance ($B = -0.14$; 95%CI − 0.29, 0.00; $p = 0.050$). Tests of simple slopes indicated that the treatment effect was non-significant among participants who had DAST-10 scores of 0 at baseline ($B = 0.13$; 95%CI − 040, 0.66; $p = 0.630$); however, the intervention significantly reduced DAST-10 scores among participants who had baseline DAST-10 scores of 4 or greater ($B = -0.44$; 95%CI − 0.87, − 0.01; $p = 0.044$). Note, scores of 4 are above the DAST-10 clinical cutoff of 3. There was no evidence of significant interactions in the prediction of DAST-10 scores at 6-month follow-up.

In the DAST model, the between-couple (Level 2) variance was non-significant and inclusion of this parameter created problems with model estimation. As such, fixed effects were estimated. This means the exponentiated regression parameter at Level 2 can be interpreted as a direct metric of the relative size of the intervention effect holding Level 1 factors constant [50]. As a result, the treatment effect at high levels of actor-reported baseline DAST scores can be interpreted as a 36% reduction in scores at 3-month follow-up (RR = 0.64). Among men who had high levels of actor DAST-10 scores at baseline, the marginal mean DAST-10 score in the control condition was 4.92, this compares to a marginal mean of 3.15 in the treatment condition, a reduction of approximately 1.77 points on the DAST-10.

## Sensitivity Analyses: Evaluating the Impact of COVID-19

Two sets of sensitivity analyses were conducted to evaluate the impact of COVID-19 on study findings. The first set of analyses excluded the last 6 couples recruited—those whose session completion was conceivably impacted

by COVID-19. The second set of analyses retained all 50 couples and incorporated a dichotomous covariate that indicated whether the follow-up was completed before or after March 15th, 2020.

When the last 6 couples enrolled were excluded, findings were stable for other illicit drug use and CAS with casual partners. Mirroring results in Table 2 obtained in the overall sample, there were no between-group differences on any primary or secondary outcomes. Furthermore, moderation analyses for other illicit drug use and CAS with casual partners yielded effects comparable in magnitude and following an identical pattern of significance as those in the full sample.

In contrast, results of moderation models predicting marijuana use and DAST-10 scores fluctuated meaningfully. When the last 6 couples recruited were excluded from the sample, there was a statistically significant 3-way interaction among actor and partner baseline marijuana use and the treatment effect on marijuana use at 6-month follow-up ($B = 0.40$; 95%CI 0.01 to 0.78; $p = 0.044$). The intervention significantly reduced marijuana use among men whose partners had high levels of baseline use—defined as 1 standard deviation above the mean or approximately 14.6 days of use in the past 30 days ($B = -2.71$; 95%CI − 4.77 to − 0.655; $p = 0.010$) and when both actor and partner use was high (B = − 1.18; 95%CI − 2.17 to − 0.20; $p = 0.018$). Meanwhile, the interaction between actor DAST-10 scores and treatment condition previously observed in 3-month follow-up data was no longer significant; however, the effect was comparable in direction and magnitude ($B = -0.10$; 95%CI − 0.27 to 0.04; $p = 0.215$).

The second set of sensitivity analyses were conducted in the full sample and included a dichotomous covariate that indicated whether the assessment took place before or after the onset of the COVID-19 pandemic. Once again, findings for other illicit drug use and CAS with casual partners were stable. Results of moderation models predicting marijuana use frequency approached those obtained in the previous sensitivity analysis. The 3-way interaction among actor and partner baseline use and the treatment effect approached significance ($B = 0.39$; 95%CI − 0.03 to 0.81; $p = 0.066$) in 6-month follow-up data. In the DAST-10 moderation model, the interaction between Actor DAST-10 scores and treatment condition was no longer significant in 3-month follow-up data; though once again the effect was comparable in direction and magnitude ($B = -0.07$; 95%CI − 0.26 to 0.12; $p = 0.455$).

## Post Hoc Power and Effect Size

Consistent with the aims of an R34-funded pilot study, the goal of this project was in part to provide effect size estimates that could be used in planning a future full-scale efficacy trial. Consistent with this, the analyses above provided important information about study power and effect size. In addition, they yielded context for the non-significant between-group differences detailed in Table 2.

Examination of effect sizes for between-group differences in the overall sample are not particularly informative. In nearly all instances, the observed mean on the outcome for the MI condition is equivalent to or greater than the observed mean for the education control condition. Conclusions about effect size drawn from the overall sample would therefore suggest that the intervention has minimal promise.

When the results of moderation analyses are considered, the pattern of between-group differences in the overall sample is not surprising. The MI condition only emerged as superior to the robust education control condition (which included psychoeducation and CHTC) among couples with the highest levels of other illicit drug use and CAS with casual partners. Therefore, significant between-group differences in the overall sample would only be expected in a future study that aims to recruit couples who fall within this zone of efficacy.

Local main effects suggest that among those couples for whom the intervention demonstrated preliminary efficacy, effect sizes are likely moderate in size and clinically meaningful. Point estimates of the treatment effect when one or both partners in the couple reported 2.5 days of use or more ranged from − 1.96 to − 2.60. If these were exponentiated as point-estimates, they would indicate the MI condition is associated with an 85–93% decrease in other illicit drug use compared to the education condition among these couples (expB = 0.14 and 0.07 respectively). The presence of couple-level variability introduces a random component to this effect size estimation; however, the lower bounds of the IRR's in all cases were 0.01, while upper bounds suggested that couples in the MI condition would likely experience reductions of 20% to 36% in most cases. Similarly, the point estimate of the treatment effect when both partners in the couple reported more than 5.1 instances of CAS with casual partners was − 2.53. Exponentiated, this would equate to a 92% reduction in CAS with casual partners and the IRR ranged from 0.01 to 0.83.

Altogether, moderation analyses and effect size estimates have two critical implications for future studies. First, in order to observe significant between-group differences, eligibility criteria should be set to insure the recruitment of couples with higher levels of drug use and sexual risk taking that used in this study. Second, post hoc power analyses were conducted using the Power Analysis and Sample Size (PASS) software program (version 19) to determine power to detect between-group differences in a Poisson distributed variable in a cluster randomized trial at any cross-sectional time-point. These indicated that a sample size of 180 couples has power > 0.80 to detect a 50% reduction in

drug use frequency and a reduction in CAS frequency of at least 60%. Based upon the observed results in this study, effects of this size are plausible. A sample of 180 would also have power > 0.80 to detect a reduction in DAST-10 scores of at least 0.5 points. While DAST-10 findings in the present study were unstable in sensitivity analyses, there is modest indication that an effect of this magnitude might be observed.

## Discussion

Despite non-significant between-group differences on all outcomes in the overall sample, results of post hoc moderation analyses provided initial evidence of the potential for MI to reduce drug use and sexual risk-taking among SMM couples who engaged in these behaviors most frequently. While intervention effects on drug use and sexual behavior outcomes were non-significant in the overall sample, moderation analyses revealed a number of promising significant effects. The couples MI intervention was associated with significant decreases in the frequency of other illicit drug use among people in couples where at least one partner had high baseline levels of use. In addition, the couples MI intervention significantly decreased the frequency of CAS with casual partners for those SMM in couples where both partners had high CAS frequency at baseline.

### Preliminary Indications that Severity May be a Determinant of Intervention Efficacy

For a number of reasons, the fact that the couples MI intervention showed effects only among couples who reported high levels of baseline other illicit drug use or CAS with casual partners is not surprising. The education control condition was highly competitive—setting a high bar for establishing preliminary efficacy. The control condition encompassed two sessions of dyadic health education and CHTC. Other interventions that utilize dyadic health education have demonstrated the potential to reduce sexual HIV transmission risk [37] or both sexual HIV transmission risk and drug use [39]. Meanwhile, CHTC alone is considered by Centers for Disease Control and Prevention (CDC) to be a proven effective public health strategy [51]. Findings provide initial indications that, for couples at greatest risk, the use of a multi-session dyadic MI intervention has the potential to produce benefits above and beyond existing dyadic treatment options.

The multi-session couples MI intervention tested here supplements existing, less intensive prevention options. For example, Starks et al. [52] developed and tested adjunct CHTC modules addressing couples' communication and substance use. These were designed to be delivered in a single CHTC session by routine HIV testers with modest additional training. While receipt resulted in significant decreases in the odds of drug use and drug-related problems; the sample of 70 SMM couples enrolled was considerably less sexually risky than the sample enrolled here. In that study, 40% of couples had monogamous agreements and only 26.4% engaged in any CAS with casual partners at baseline. While the couples MI intervention in the current study requires considerable training and MI skill, it was able to demonstrate significant reductions in CAS with casual partners among those men engaging in the highest frequency of this behaviour—perhaps as a result of its complexity. Accordingly, this couples MI intervention sits alongside less intensive interventions, as an option optimized for men at greater risk.

### Moving Beyond the Identified-Client Paradigm

Findings indicated that the couples MI intervention reduced the frequency of other drug use when at least one partner in the couple used with high frequency. One of the challenges in previous studies of couples approaches to MI for substance use was how to respond when partners had opposing perspectives on change [27]. The fact that the intervention showed promise in reducing drug use in circumstances where one or both partners had high levels of use provides initial indications that the framework for conducting MI with couples outlined by Starks et al. [28, 53] has the potential to address some of the provider challenges identified in previous studies.

### Intervention Implications

These findings contribute to a growing body of research that has supported or is currently testing the general premise that risk reduction interventions for SMM in relationships benefit from the incorporation of relationship skills training [36, 37, 52–57]. Many of these interventions rely on agreement formation as their hypothesized mechanism of change. This proposition is broadly consistent with Interdependence Theory [30, 31]. In articulating a MI process for facilitating relationship functioning and identifying techniques to minimize discord while discussing a joint goal, the work of Starks et al. [28, 29] may inform other existing intervention options by providing a framework for understanding provider responses in situations where partners disagree about change. This may help to identify common factors or mechanisms of change that generalize across existing dyadic interventions.

At the same time, the reach of dyadic interventions may be limited. Not all couples may be willing or able to engage

in substance use or HIV risk reduction counseling together as a couple. Some evidence suggests that the demands of dyadic participation may present barriers particularly for couples with relatively poorer relationship functioning [58, 59]. There is also evidence that more established couples may perceive themselves to be low risk and therefore consider HIV prevention research as less applicable or suitable to them [60]. Furthermore, MI may not be needed by couples with relatively lower (but non-zero) levels of drug use or HIV transmission risk behavior. There continues to be a role for tailored individual intervention options [53] and scalable lower-intensity interventions [37, 52, 57, 61] alongside this work on couples MI.

### Summary of Strengths and Limitations

This was the first randomized controlled trial of a couples MI protocol based upon the theoretical framework proposed by Starks et al. [28, 29]. The study had a number of methodological strengths. The trial utilized a robust alternative treatment control condition comprised of psychoeducational content and including CHTC. MI and control conditions were administered by different staff to reduce the likelihood of cross-contamination. Detailed self-report data was gathered through TLFB interviews administered by an RA who was masked to condition and further corroborated by biological markers of drug use and sexual risk taking. Moderation analyses were conducted within the APIM framework. This approach is aligned with current conventions for the handling of dyadic data and also provided critical information about the couples for whom the intervention has the greatest potential.

These findings should be viewed in light of the following limitations. First, the COVID-19 pandemic disrupted session completion for the last 6 couples enrolled, necessitated the switch to remote follow-up completion and the suspension of biological specimen collection. Five of these last 6 couples were randomly assigned to the MI condition. While the majority of findings were robust in sensitivity analyses, it is plausible that COVID-19 may have exacerbated between condition differences in session retention and thereby attenuated treatment effects to some extent. Second, conclusions about factors associated with session retention and follow-up completion—including the impact of COVID-19—should be viewed with caution. Comprehensive and systematic data on reasons for session and follow-up retention were not available. Third, all main effects of the MI intervention were non-significant in the overall sample and promising intervention effects were only observed in moderation analyses. Any subsequent efficacy trial should be conducted with a sample comprised of uniformly higher risk couples in order to provide a robust assessment of the intervention's overall main effects. Fourth, it was not possible to achieve uniform success in masking participants to condition assigned due to the differences inherent to the experience of the MI and education conditions. This introduces the potential for bias to arise from participant-related expectancies or socially desirable responding. This limitation is shared by a range of comparable studies testing behavioral interventions for drug use and sexual risk [e.g., 62–64]. It is potentially mitigated to some extent by the use of biomarkers to corroborate self-report data.

Finally, this was a pilot study with modest sample size intended to test preliminary efficacy and provide effect size estimates necessary to plan a larger trial. The trial was not originally designed with the express intent to conduct moderation analyses. While hypotheses of moderation were theoretically grounded, these analyses were proposed post hoc to contextualize the non-significant effects of treatment in the overall sample. Results here warrant replication in future research with larger sample size. In addition, the sample was recruited from a large urban center and may not be representative of the wider US population of partnered SMM. Reflecting the epidemiology of HIV infection, at least one partner in each couple was 18–29, and therefore findings may be most relevant to, or representative of, this emerging adulthood developmental stage. Due to COVID-19, the collection of follow-up STI specimen data was curtailed, diminishing our ability to test associations of the intervention with this biological outcome.

## Conclusions

This study provided initial evidence that an MI approach modified for couples [28, 29] has the potential to significantly reduce drug use and sexual risk-taking among the highest risk SMM couples. By drawing upon Interdependence Theory, this framework addresses challenges experienced in previous applications of MI with couples and is a starting point for identification of dyadic mechanisms of change that generalize across couples HIV and substance use risk reduction interventions. While the results of this pilot randomized controlled trial necessarily need to be replicated in a larger efficacy study, these results point to the promise of such continued investigation. While the couples MI intervention tested here is comparatively more intensive than some existing interventions, in terms of duration or clinical skill complexity, it potentially fills a critical intervention gap, providing an option appropriate for SMM couples with the highest need for behavioral risk reduction.

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**Author Contribution** TS led initial study design and was primarily responsible for designing and executing analyses, drafting text, and submitting the final manuscript. TA, KK, MS, and BM drafted text. KI and MG added and reviewed content.

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**Data Availability** Data not publicly available. Please contact the corresponding author.

**Code Availability** Descriptive statistics and analyses of randomization and attrition were conducted using SPSS version 25. Models were calculated in Mplus version 8.1.

## Declarations

**Conflict of interest** The authors declare they have no conflicts of interest or competing interests.

**Ethics Approval** The study was approved by the Institutional Review Board at Hunter College, and was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

**Informed Consent** All participants were provided written informed consent information and this was reviewed verbally prior to the start of the study. Participants provided written documentation of consent at baseline.

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